

Bankhead Coley Cancer Research Program and James & Esther King Biomedical Research Program

FY 2014/2015 Funding Opportunity Announcement Questions and Answers

August 14, 2014

- Can there be more than one page of images, graphs and tables?
 Yes. Researchers may upload one document. The document may have several pages if
 absolutely necessary (if the figures go over one page). Figure legends need to be included in
 the document.
- I had submitted an LOI for a Discovery Science project, but would now like to submit a
 proposal with a different title and different aims. Is this possible?
- 3. I want to change the title, but keep the same aims and same funding mechanism (e.g., I submitted a Discovery Science project to Bankhead-Coley and I want to change the title, but not the aims). Can I do this?
 Yes.
- 4. Can the same PI submit a Bridge grant and a Discovery Grant for 2 different projects to the same program (Bankhead Coley)?
 No. For this Funding Opportunity Announcement, researchers may only submit one application to Bankhead-Coley, and one application for King as the Principal Investigator.
- Can we redirect an LOI from Bankhead Coley to James and Esther King if it fulfills the requirement for that program? No.
- 6. In my LOI, I stated my research priority targeted Prevention and Treatment. However, after just reading the clarifications to relevant questions (posted 08/07/14), it seems that my project (which relates to brain cancer) does not meet the requirements for this Priority. However, my project does have relevance/applicability to the Screening Priority where there is no limitation regarding specific cancer subtypes. Thus, is it OK to edit/switch my priority at this point despite what I listed on my original LOI?
 Yes, you can revise the priority when you submit your application. If you are not changing
 - the project, but have decided the same project fits better with a different priority you can change the priority you specify.
- 7. I have submitted two LOI for 2 different projects/mechanisms (1 discovery and 1 clinical) to Bankhead-Coley. Is it possible to switch one of them to King when I submit the grant?

 No. Researchers may only submit one application per funding program.
- 8. Am I correct that the proposal is limited to 12 pages and that the preliminary data are limited to one page. It was also mentioned that the graphics/images need to be uploaded separately.

How exactly will the graphs/images loaded separately be counted against the page/word limit? As you know, a lot of preliminary data are graphs/images.

Follow the guidelines on the online application system. We will issue an addendum to the Funding Opportunity Announcement.

9. On table 2: Grant Application Components and Page limits. A section for letters of support is not listed yet on the website there is an option to upload these letters. Are we allowed to submit letters of support and if yes, what is the page limit per letter and what is the maximum amount of letters we can submit.
Letters of support from the Tobacco Free Florida program are required when conducting research involving behavioral health and tobacco use. They are optional for other research. If researchers select the option that indicates they are conducting behavioral health research

involving tobacco use, they will see an option to upload a letter of support. If you do not see

10. The guidelines stipulate that applications should describe:

this option, contact program staff for technical assistance.

"A scientific advisory process involving researchers from at least two of the major cancer centers in Florida, and at least two regional cancer centers." Would we need to list 2 other major Cancer Centers besides ourselves? Please confirm that regional specifies that we can only include cancer centers within Florida and do these centers have to conduct research? Yes, you would need to list 2 other major cancer centers in Florida besides your institution. The scientific advisory process must involve researchers from at least two academic medical centers that receive direct appropriations for biomedical research from the Legislature, and at least two hospitals considered regional cancer centers.

- 11. It is my understanding that this "document", containing the figures + legends, is separate from the Research plan and it is included in the 12 page limit.

 See the answer to question 8.
- 12. If appendices are allowed, where should it be included and/or uploaded? Would unpublished manuscripts, which are relevant to the application, in this appendix be allowed? Is there a page limit for the appendix? Appendices are not allowed.
- 13. Can one proposal for which LOI was submitted for Bankhead-Coley be switched to James and Esther King program?
 No.
- 14. I am preparing a submission for the Bankhead Coley funding opportunity, and have a question regarding the character limits described in the program announcement. Are the character limits given in Table 2 (see attached) including spaces, or are spaces excluded from the character limit?

Follow instructions in the application about word limits.

- 15. Having reviewed the first group of Answers to Questions just published, we note that QA16 states that researchers may only submit one application to Bankhead-Coley, and one application for King as the Principal Investigator. This was not the understanding we obtained from the RFA and some of our researchers have submitted two LOIs for Bankhead-Coley. Is it possible for those PIs to submit one of their projects as a full application to King instead, provided it is tobacco-related? If so, do you need to receive a revised LOI to confirm this intent?
 No.
- 16. Is Florida small business entity eligible to apply as PI?

Any researcher at a university or research institute in Florida is eligible to apply. Researchers at small business entities are not eligible, unless they otherwise are researchers at universities or research institutes in Florida.

- 17. The guidelines (pgs.17-18) for the Bankhead-Coley and James and Esther King addressed that there shouldn't be scientific or financial overlap between projects, but didn't explicitly state a PI couldn't submit two distinct projects in response to Bankhead-Coley. So, PI submitted two distinct LOI for BC program. In the first group, Q&A #63 states that only one submission per mechanism is allowed. Can one proposal for which LOI was submitted for BC be switched to JEK mechanism?
 No.
- 18. Are tobacco use/smoking proposals fundable as Bankhead-Coley grants? All applications for must be responsive to one of the research priorities listed within the Bankhead-Coley funding opportunity.
- 19. For Financial Interest form, it only has "Principal Investigator." Are co-Pls required to fill this form as well?
 - The Principal Investigator must disclose any financial interests that the researcher, the researcher's immediate family, or any other personnel on the grant (sub-investigators and research staff) and their immediate families, have related to the research. If funded, financial disclosures for all personnel must be submitted.
- 20. Most of the statements in the FOA's "Screening" Priority refer to screening of humans for early detection of cancer or preventable cancer. Would "Screening" also include environmental assessment/screening mechanisms of environmental conditions associated with risk of cancer or tobacco-related diseases?
 Environmental assessments can be included if they are used for early detection of cancer or preventable cancer in humans.
- 21. According to the FOA, "Clinical Research" can involve behavioral health interventions. Can it also include environmental interventions that directly "involve a particular person or group of people" in reducing exposure to risk conditions?
 Clinical trials are prospective biomedical or behavioral studies on human subjects that are designed to answer specific questions about the safety and efficacy of an intervention (such as a drug, device or behavioral health intervention). Manipulations of the subject or the subject's environment that are performed for research purposes, and communication or interpersonal contact between investigator and participant may be considered clinical investigations.
- 22. The LOI I have submitted is for a clinical trial for patients with rectal cancer. I have assumed that this is a site disease which will be eligible for Bankhead Coley grant since colon cancer is identified as a priority.
 - Yes, rectal cancer qualifies under colon cancer.
- 23. FOA p. 27 (#3) says pictures and objects can be included in documents for online application form, except no drawings in Project Title, General Audience Abstract and Scientific Abstract. Does this mean that for all other sections/categories, that tables, graphs and images can be embedded into text and submitted in that category (e.g. Research/Project Plan or category K)? If that is the case, what is "Upload Table, Image or Graph" on submission page for? It is not possible to include images, graphs, or tables in the text in other sections of the application.
- 24. FOA, p. 28 (#3) says that summary of character and page number limitations are given in I.5, Table 1. Do you mean Table 2 of II.3? If not the latter, where do I find this information -- Table 1 only gives important dates.

- Follow the guidelines on the online application system. We will issue an addendum to the Funding Opportunity Announcement.
- 25. FOA p 28 (#4) says that application must contain all required sections in I.5, Table 1. Do you mean Table 2 of II.3?
 Follow the guidelines on the online application system. We will issue an addendum to the Funding Opportunity Announcement.
- 26. FOA p. 20 category H is for "Table of Contents." Where is this submitted in the online form? Table of Contents is not required. We will issue an addendum to the Funding Opportunity Announcement.
- 27. FOA p. 20 lists category I for "Resources." Where is this on the online form, and what information is to be included here? Resources can be described in the "Facilities and Other Resources" section of the online application.
- 28. Can a researcher be listed as key personnel on two different Bankhead-Coley grant applications as long as the projects are completely different and effort is not over-committed? Yes. A researcher can be a principal investigator on only one application per program. However, they may serve as a co-PI or other role on other applications, provided they are not over-committed.
- 29. Is the bridge budget only to be in a 6 month proposed format or do you need to see the entire 5 year budget based on the RO1 we are applying for bridge funding? The application only needs to include the 6 month budget for the grant.
- 30. Where may we upload / input figures? The research proposal goes into a text box. There is a place that gets checked indicating we wish to upload figures but don't see where it can actually be uploaded.
 Figures may be uploaded as an attachment in the Upload tables, images or graph section.
- 31. Is the TTF mechanism allowing a budget of 1.5M? Do we select which mechanism we submit the TTF application? The primary objective of the technology transfer funding (TTF) priority is to assist investigators in moving promising research findings toward commercialization. The TTF priority can be responsive to any of the four mechanisms listed in the Funding Opportunity Announcement.
- 32. Are applicants allowed to designate multiple principal investigators for a single grant application?

 There needs to be one designated Principal Investigator. Additional researchers would be listed at Co-Principal Investigators. There can be multiple collaborators on a project, but there must be only one principal investigator.
- 33. The following set of questions in in response to the following statement in the call for applications: "Work Must Occur in Florida: All activities funded through this competition must occur in Florida. All work (effort) must occur and 100% of funds must be spent in Florida at the applicant organization and any collaborating entities."
 - Are grantees allowed to purchase necessary lab equipment that is only available from other states.
 - Are grantees allowed to pay for laboratory analyses such as blood work in other states?
 - Are grantees allowed to pay renowned expert consultants who live out of state?
 - Are grantees allowed to pay out of state participants?
 - Are grantees allowed to purchase plane tickets that are purchased outside the state of Florida (that is, the airlines are not located in Florida)?

Activities funded through this competition must occur in Florida. All work (effort) must occur and funds must be spent in Florida at the applicant organization and any collaborating entities. However, the Department may allow exceptions if the researcher can demonstrate the service is essential and only provided outside the state, and if the amount is less than 10% of the requested amount.

- 34. In the Funding Opportunity Announcement it is stated in the overview that the purpose of the program is "to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease..." However, tobacco-related cardiovascular disease, stroke, and pulmonary disease appear to be absent from this year's list of research priorities, unless related to cancer. Please clarify whether cardiovascular disease (the number one cause of death in the U.S.), stroke, or pulmonary disease in the absence of cancer remains a priority. A follow up question to this: If cardiovascular disease, stroke, and pulmonary disease in their own rights are indeed not priorities, please explain the rationale for their exclusion, as the combination of deaths of Floridians from these three conditions exceeds deaths of Floridians by cancer. The Biomedical Research Advisory Council (BRAC) advises the State Surgeon General as to the direction and scope of the biomedical research program. The responsibilities of the council may include, but are not limited to:
 - Providing advice on program priorities and emphases.
 - Developing criteria and standards for the award of research grants.

The priorities listed in this funding opportunity were developed by the BRAC based on the Strategic Goals and Tactics developed in 2014 developed over the course of a year in public meetings. Funding opportunity announcements may vary in areas of focus and in the types of funding mechanisms offered, but will be based on the Strategic Research Goals, available at: http://www.floridahealth.gov/provider-and-partner-resources/research/FINAL-BRAC-Strategic-Goals-and-Tactics.pdf

- 35. Do all personnel working on the grant have to become a member/have an account and sign a reportable financial interests form? If so, what about personnel on the grant that is not requesting any salary? If no salary is requested do the letters of support have to include that? The Principal Investigator must disclose any financial interests that the researcher, the researcher's immediate family, or any other personnel on the grant (sub-investigators and research staff) and their immediate families, have related to the research.
- 36. I am working on preparing submissions for your James & Esther King research program, and I have a question on an allowable cost. After reviewing the grant instructions and your website, I was unable to determine if graduate student tuition is an allowable cost on your grant. Can you please let me know if this is allowable to request on a grant submission. Tuition is an allowable cost.
- 37. In the Funding Opportunity Announcement FY 2014-2015 (James & Esther King), page 11, it says "All applications addressing tobacco use must include a letter of support from The Tobacco Free Florida Program." My question is: I plan to propose the use of research cigarette smoke extract for treating cultured human cells, do I need a letter of support from The Tobacco Free Florida Program? Cigarette smoke extract is made by bubbling the cigarette smoke through cell culture medium via a pump. The cell culture medium containing the cigarette smoke will be applied to cell culture during the cell growth.

No. Discovery science does not require a letter of support from Tobacco Free Florida. Behavioral health studies involving tobacco require a letter of support. We will issue an Addendum.